

Remarks

The above identified application has been carefully reviewed and amended in light of the Examiner's office action mailed on April 5, 2007, which sets a two month period for response. A one month extension of time to respond to the office action is hereby requested, and the requisite fee is enclosed, thereby extending the deadline for response to July 5, 2007.

The Examiner has stated that mentioning the references in the specification is not a proper information disclosure statement. Applicant submits that an Information Disclosure Statement was filed on March 20, 2007, a copy of which is enclosed. A copy of a return postcard indicating receipt of the Information Disclosure Statement by the U.S. Patent and Trademark Office on March 23, 2007 is also provided.

In view of the above, Applicant respectfully requests that all of the documents cited in the Information Disclosure Statement be considered and made of record in the above-identified application.

Without conceding the correctness of any of the Examiner's rejections, applicant has amended the present claims to clarify the invention and to facilitate the prosecution and allowance of the above-identified application. Applicant expressly reserves the right to seek patent protection for the original claims and

for any other claims that are supported by the present specification in one or more later-filed related applications.

Claims 39, 60 and 66 have been rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner objects to the expressions "at least partially" and "substantially free of the water-containing gel."

Each of claims 39, 60 and 66 have been amended by replacing the phrase "at least partially" with the term "adjacent" and by deleting the phrase "the border being substantially free of the water-containing gel." Applicant submits that each of these amendments is fully supported by the specification as filed, for example, in the specification and/or drawings of the application.

Applicant submits that each of claims 39, 60 and 66 satisfies the requirements of 35 U.S.C. 112, second paragraph, and respectfully requests that the rejection of these claims based on this statutory provision be withdrawn.

Independent claims 33, 55 and 61 have been amended by changing "the back of a woman" to "an upper back of a woman". This amendment is fully supported by the specification and the drawings of the subject application. Dependent claim 56 has also been similarly amended in order to provide proper

antecedent basis in light of the amendment to independent claim 55.

Claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Presentation of Kobayashi Healthcare, Inc. (Kobayashi), in view of any of JP 2002119529 (JP '529) and U.S. Patent No. 6,224,899 (U.S. '899). Applicant traverses this rejection as it relates to the present claims.

The present invention is directed to methods of treating hot flashes associated with menopause in a woman. The methods generally comprise placing at least one cooling device at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes. Independent claim 33 defines embodiments of the invention which comprise providing at least one cooling device in a package and instructing the woman to place the cooling device at a location on the upper back. Independent claim 55 defines embodiments of the invention in which the cooling device comprises a water-containing gel. Independent claim 61 defines embodiments of the invention which comprise removing the at least one cooling device from a package.

A hot flash associated with menopause is often experienced by a woman as a wave-like warming sensation usually radiating from the front of the chest to the head and sometimes into the hands. This wave-like warming sensation can be highly unpleasant, even embarrassing due to a flushing of the face, and

can last up to five minutes. Applicant has discovered that by placing a cooling device specifically on an upper back of a woman experiencing a hot flash, for example, on a location between the shoulder blades or on a region located between the C3 vertebrae and the T6 vertebrae of such a woman, as recited in certain of the present dependent claims, the hot flash can be successfully treated, for example, the wave-like warming sensation significantly lessened in intensity or even eliminated.

Further, the claimed methods allow a woman to easily and discreetly treat menopausal hot flashes at virtually any time and/or place. For example, application of the least one cooling device to the upper back is not only effective in reducing or eliminating the hot flash symptoms, but the upper back, being a discreet location of the body, advantageously facilitates privacy in that the at least one cooling device can be discreetly concealed under clothing. Thus, the present methods very effectively treat menopausal hot flashes, and do so without embarrassing the woman. This combination of advantages, achieved in accordance with the present invention, gives the woman more comfort and more confidence.

Kobayashi discloses a consumer-opinion research report conducted for Kobayashi Healthcare, Inc. A portion of the report discloses "Cooling Gel Sheets for Hot Flashes and Cooling Pads for Adults."

Kobayashi does not disclose, teach or suggest the present invention. For example, Kobayashi does not disclose, teach, or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing at least one cooling device in a package and instructing a woman to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 33.

Similarly, Kobayashi does not disclose, teach or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device, comprising a water-containing gel, at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 55.

In addition, Kobayashi does not disclose, teach or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 61.

As recognized by the Examiner, Kobayashi does not disclose, teach or even suggest instructing a user to place the cooling

device on any specific site, let alone on the upper back of the woman, as recited in the present claims. Kobayashi provides no motivation, nor any other reasonable, proper basis, for making obvious the present invention. Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art even consider the present methods, including, for example, the step of instructing a woman to place a cooling device at a location on an upper back (claim 33), or placing a cooling device at a location on an upper back (claims 55 and 61). Thus, applicant submits that the rejections based on Kobayashi are derived from an improper hindsight view of applicant's own disclosure and invention.

JP '529 discloses a cooling patch which cools a localized lesion, bruise or sprain.

JP '529 does not disclose, teach or suggest the present invention. For example, JP '529 does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes including instructing the woman to place a cooling device at a location on her upper back (claim 33) or placing a cooling device at a location on the upper back of the woman (claims 55 and 61), as recited in the present claims.

Applicant further submits that JP '529 does not supply the substantial deficiencies apparent in Kobayashi and, therefore, the combination of Kobayashi in view of JP '529 does not render the present claims unpatentable.

Further, the treatments disclosed in JP '529 using a cooling patch to treat a localized lesion, bruise or sprain are not in the least comparable to or even remotely suggestive of the presently claimed methods of treating a systemic condition, namely hot flashes associated with menopause in a woman. As discussed hereinabove, a hot flash associated with menopause is commonly experienced as a warming in the chest which radiates into the head and sometimes the hands. A lesion, bruise or sprain has nothing in common with menopausal hot flashes. Such a lesion, bruise or sprain can occur at any body area, is by nature a condition that is localized to a specific area on a body, often away from the upper back of the body, and is dramatically different from the systemic, hormonally induced, sudden, wave-like warming sensation experienced as a result of a hot flash associated with menopause.

Treatment of a localized lesion, bruise or sprain by applying a cooling patch to the site of the lesion, bruise or sprain is not in the least suggestive of treating a woman experiencing a menopausal hot flash or prone to experiencing such hot flashes by instructing the woman to place a cooling device at a location on her upper back or placing a cooling

device at a location on her upper back, as recited in the present claims.

Neither Kobayashi nor JP '529, alone or in combination, discloses, teaches or even suggests a method of treating hot flashes associated with menopause in a woman experiencing a hot flash or prone to experiencing such hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65 are unobvious from and patentable over Kobayashi in view of JP '529, under 35 U.S.C. 103.

Further, U.S. '899 does not supply the substantial deficiencies apparent in Kobayashi with regard to the present claims.

U.S. '899 discloses an adhesive cooling gel composition which contains water and which provides a cooling effect and/or coolness-preserving effect. U.S. '899 discloses that the adhesive cooling composition can be applied to the forehead of a subject which is feverish, and can be used to cool eyes, cheeks, jaws and feet, or can cool inflammatory parts to assuage pain when suffering from blow pain, sprain or muscular pain.

U.S. '899 does not disclose, teach or suggest the present invention. For example, U.S. '899, like JP '529, does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods of treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

As discussed hereinabove with regard to JP '529, applying a cooling device to a specific site, as taught in U.S. '899, in order to treat the specific site is not even remotely suggestive of methods of treating hot flashes associated with menopause in a woman experiencing a hot flash or prone to experiencing such hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman.

Further, U.S. '899's treatment of feverish subjects, which involves placing a cooling composition on a forehead of a person who is feverish, is not even remotely suggestive of methods of treating hot flashes associated with menopause in a woman, as recited in the present claims.

Neither Kobayashi nor U.S. '899, alone or in combination, discloses, teaches or even suggests a method of treating hot

flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65, are unobvious from and patentable over Kobayashi in view of U.S. '899 under 35 U.S.C. 103.

Claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of JP '529 or U.S.'899 each in view of U.S. Patent No. 5,730,957 (U.S. '957). Applicant traverses this rejection as it relates to the present claims.

As discussed hereinabove, neither JP '529 nor U.S. '899 discloses, teaches or even suggests any methods of treating hot flashes associated with menopause in a woman. U.S. '957 does not supply the deficiencies in JP '529 and U.S. '899 with regard to the present claims.

U.S. '957 discloses a composition for providing a supply of a water-based cool mixture and a pressurized canister containing such a cool mixture.

U.S. '957 does not disclose, teach or suggest the present invention. For example, U.S. '957 does not disclose, teach or

even suggest methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

The Examiner recognizes that neither of JP '529 nor U.S. '899 teaches treating hot flashes. The Examiner then cites U.S. '957, which suggests a cool spray can be used to treat a wide variety of conditions including sunstroke, sunburn, fever, muscle fatigue and hot flashes, as teaching that "the art has recognized using cooling techniques to treat fever, hot flashes and muscle strain equally...in terms of treating them using the same cooling methods and devices."

Applicant submits that even if the art has recognized using cooling techniques to treat a wide variety of conditions, including hot flashes, the art has not recognized or even suggested treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman. In fact, none of the art has even suggested treating any systemic condition, let alone hot flashes associated with menopause, as recited in the present claims. Moreover, using a spray to treat hot flashes can be downright embarrassing for the menopausal

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woman and is certainly not as effective for an extended period of time in treating the hot flash, nor as discreet as a cooling device on the upper back of the woman discreetly hidden from view by clothing.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65, are unobvious from and patentable over JP '529 and U.S. '899 in view of U.S. '957 under 35 U.S.C. 103.

Claims 39, 60, and 66 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi with any of JP '529 or U.S. '899 and further in view of U.S. Patent No. 3,811,438 (U.S. '438). Applicant traverses this rejection as it relates to the present claims.

The disclosures and deficiencies of each of Kobayashi, JP '529 and U.S. '899 have been discussed in detail previously. Such discussions are resubmitted here.

U.S. '438 relates to adhesive bandages.

U.S. '438 does not disclose, teach or suggest the present invention. For example, U.S. '438 does not disclose, teach or even suggest any methods of treating hot flashes associated with menopause in a woman, let alone methods of treating such hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on

her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

Simply put, U.S. '438 does not supply the deficiencies apparent in the teachings of Kabayashi, JP '529 and U.S. '899.

In view of the above, applicant submits that the present claims, and in particular claims 39, 60 and 66, are unobvious from and patentable over Kobayashi in view of any of JP '529 or U.S. '899, and further in view of U.S. '438, under 35 U.S.C. 103.

Claims 39, 60, and 66 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of any of JP '529 or U.S. '899 each with U.S. '957 and further in view of U.S. '438. Applicant traverses this rejection as it relates to the present claims.

The disclosures and deficiencies of each of these references have been discussed in detail previously. Such discussions are resubmitted here.

Applicant submits that, in light of the above, none of these references, alone or in any combination, disclose, teach or suggest the present invention. For example, none of the references, alone or in any combination, disclose, teach or even suggest methods of treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to

place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 39, 60 and 66, are unobvious from and patentable over the combination of any of JP '529 or U.S. '899 each with U.S. '957 and further in view of U.S. '438, under 35 U.S.C. 103.

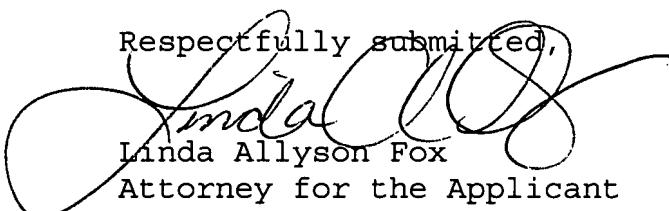
In addition, applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, the prior art does not disclose, teach or suggest the present apparatus and systems including the addition feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims, that is, claims 33, 35, 36, 38, 39, 41, 44, 45 and 55-66, are unobvious from and patentable over the prior art under 35 U.S.C. 103. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date.

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Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

  
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